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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,468	07/10/2003	Patrick M. Hughes	17549(OCU)	3251

51957 7590 10/29/2010

ALLERGAN, INC.
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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
10/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents_ip@allergan.com

Office Action Summary	Application No.	Applicant(s)	
	10/617,468	HUGHES ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-16 and 21-31* is/are pending in the application.

4a) Of the above claim(s) *26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8-16, and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 October 2010 has been entered.

Response to Arguments

As a primary matter, the 35 USC section 112 rejection is hereby withdrawn in view of applicants' withdrawal of claims 2, 3, 7, and 17.

Further, claims 1-3, 7-9, 12 and 15 stand rejected under 35 U.S.C. § 103(a) as obvious over Wilkin, J., Allergan, Inc. Avage (tazarotene) cream, 0.1% Irvine California 92612, USA (2002), printed pages 1-17 (especially page 1) ("Wilkin") (Office Action, page 7) due to the fact that the Wilkin reference adequately discloses substantial support of treatment with tazarotenic acid to the periocular portion to the eye.

Applicants contend still that Wilkin does not disclose all the claim limitations and beyond not suggesting that the claimed method be carried out, actually teaches away from it.

Applicants' arguments are considered but are not found persuasive due to Wilkins explicitly teaching tazarotenic acid to the periocular and peribulbar region of the eye.

Applicants' claims are absent of any other suitable method by which the said active agent would be administered to the posterior portion of the eye.

Whether recognized or not, the effect of tazarotenic acid to the eye is no less occurring. The Raghava et al. article accompanying the current set of remarks (1 October 2010) describes periocular routes as inclusive of subconjunctival, sub-tenon, retrobulbar, peribulbar and posterior juxtascleral. In the instances of peribulbar and posterior juxtascleral, the methods of applying the said agent by Wilkin is still obvious over the claimed invention.

Further, the mere mention of Wilkin teaching away from the claimed invention does not negate the fact that Wilkin et al teach tazarotenic acid to the region surrounding the eye. The region surrounding the eye reasonably constitutes either peribulbar, periocularly and/ or posterior juxtascleral application. In either event, muscles surrounding the eye are involved in the taking-up of the active drug. Thus, the one of skill would reasonably come to the conclusion that due to the potency of the active agent that suitably the posterior portion of the eye would be affected in some way.

Further, by virtue of Wilkin teaching the application to the periocular and peribulbar routes of administration *still* fully encompasses the claimed invention. A posterior juxtascleral injection would still be encompassed by periocular administration according the Raghava article.

Status of the Claims

Claims 1, 8-16, and 21-25 are pending further prosecution on the merits. Claims 26-31 are withdrawn from further consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-16, and 21-25 are unpatentable over Wilkin, J. (Wilkin, J. (Allergan, Inc. Avage (tazarotene) cream, 0.1% Irvine California 92612, USA (2002), printed pages 1-17, especially page 1) (already made of record in previous action).

Wilkin teaches Tazarotene for use in treating fine wrinkling, facial mottled hypo- and hyperpigmentation and benign facial lentigines. See the second paragraph under Clinical Pharmacology. Tazarotene is a retinoid prodrug that converts to its active form tazarotenic acid. See the first paragraph under Clinical Pharmacology. Application of the drug is once a day. It is obvious that fine wrinkling will occur in the periocular or peribulbar region, hence the use of the Tazarotene around the eye to some extent would be obvious when the product is used.

Applicant claims a method of sustained-delivery of a retinoid to treat a disease condition that can be treated by the retinoid. The retinoid ester prodrug is administered periocularly as an ester prodrug that converts to the active retinoid. Regarding the limitation of "sustained delivery" it is noted that the specification at page 8, lines 23-30, that delivery to the periocular space will result in "sustained delivery of the drug to the back of the eye..." Regarding the claim limitation of delivery of the active drug to the posterior part of the eye, it is understood that application of the retinoid prodrug to treat fine wrinkles in the manner of the prior art would obviously perform this function. In this regard, the claims do not require that the disease actually be a disease of the eye. There is

a disconnection between the disease and the treatment. As such, the prior art renders obvious the claimed invention. Regarding claim 15, the term "peribulbar" can be defined to mean the area around the eye and does not necessarily mean within the eye itself.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627